

SECTION 3
Summary of Safety and Effectiveness

Sponsor: EMcision, Ltd.

K 07 1103

Contact Person: Nagy Habib, MD
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United Kingdom

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Summary Prepared: April 10, 2006

JUN 27 2007

Trade Name: Habib Hexablate

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification: Class II per 21 CFR 878.4400

Product Code: GEI

Predicate Devices: Habib 4X (K051420)

Intended Use:

The Habib Hexablate is intended to be used to assist in coagulation of tissue during intraoperative surgical procedures.

Description:

The Habib Hexablate is a bipolar radiofrequency (RF) device that consists of a handle and an array of seven parallel electrodes which extend out from the handle. The electrode configuration consists of six electrodes in a ring and one electrode in the center of the ring. The Habib Hexablate has an attached cable which connects the device to the Habib Hexablate Switch Unit and then to an RF Generator. The electrodes are inserted into tissue and the tissue is coagulated using RF power. The Habib Hexablate is designed for use in surgery and is a single use device.

Technological Differences:

The Habib Hexablate has the same basic technological characteristics as the Habib 4X. Both devices use bipolar RF energy through a number of electrodes to create a volume of coagulated tissue. The primary difference is in the size and shape of the coagulation zone created by each

device. The Habib Hexablate also uses aspiration through the center electrode to remove fluids and gases from the center of the coagulation zone.

Performance Data:

Performance testing was done to ensure that the Habib Hexablate functions as intended and meets design specifications. Sufficient data was obtained to show that the device is substantially equivalent to the predicate device, and meets safety and effectiveness criteria.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EMcision, Ltd.
% Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
455 East Trimble Road
San Jose, California 95131-1230

JUN 27 2007

Re: K071103

Trade/Device Name: Habib Hexablate
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 7, 2007
Received: June 12, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

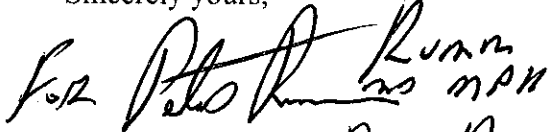
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Morten Simon Christensen

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Handwritten notes: Run in MPH, DEP D. REC, 8/8, 6/27/07

Enclosure

SECTION 2
Indications for Use Statement

Indications For Use Statement

510(K) Number (if known) K071103

Device Name Habib Hexablate

The Habib Hexablate is intended to be used to assist in coagulation of tissue during intraoperative surgical procedures

Prescription Use ☒ OR Over the Counter Use ☐
(per 21 CFR 801.109)

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K071103